

Food and Drug Administration, HHS

§ 530.1

appropriate exposure times for the specific lots of fish under prevailing conditions.

(ii) *Amphibians and other aquatic cold-blooded animals.* The drug is added to ambient water in concentrations of from 1:1000 to 1:20,000 depending upon species and stage of development.

(2) *Indications for use.* For the temporary immobilization of fish, amphibians, and other aquatic coldblooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

(3) *Limitations.* Do not use within 21 days of harvesting fish for food. Use in fish intended for food should be restricted to Ictaluridae, Salmonidae, Esocidae, and Percidae, and water temperature exceeding 10 °C (50 °F). In other fish and in coldblooded animals, the drug should be limited to hatchery or laboratory use.

[79 FR 10974, Feb. 27, 2014]

§ 529.2620 Triptorelin.

(a) *Specifications.* Each milliliter of gel contains 100 micrograms (mcg) triptorelin as triptorelin acetate.

(b) *Sponsor.* See No. 051233 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine—(1) Amount.* Administer 200 mcg intravaginally approximately 96 hours after weaning.

(2) *Indications for use.* For the synchronization of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination.

(3) *Limitations.* Not approved for use in gilts. Safety and effectiveness have not been evaluated in these animals. Should not be used in sows with obvious reproductive tract abnormalities.

[77 FR 64717, Oct. 23, 2012]

PART 530—EXTRALABEL DRUG USE IN ANIMALS

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AUTHORITY: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e.

SOURCE: 61 FR 57743, Nov. 7, 1996, unless otherwise noted.

Subpart A—General Provisions

§ 530.1 Scope.

This part applies to the extralabel use in an animal of any approved new animal drug or approved new human drug by or on the lawful order of a licensed veterinarian within the context of a valid veterinary-client-patient relationship.